



Evans, J. T., & Whitehouse, M. R. (2020). A review of registry research from 2020. *Bone & Joint 360*, 9(6).
<https://doi.org/10.1302/2048-0105.96.360818>

Peer reviewed version

Link to published version (if available):
[10.1302/2048-0105.96.360818](https://doi.org/10.1302/2048-0105.96.360818)

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BJ360 registry review - September 2020

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Introduction

The first Registry Review focused on data and results from analysis of arthroplasty registers, in this, the second Registry Review, we have expanded the remit to include non-arthroplasty registries. This month, we also feature the recently published protocol of a randomised controlled trial nested within an arthroplasty registry, an important study design that is likely to form an important efficient study methodology in registry research. The most notable recent development for academics working with arthroplasty registry data, however, is a simple change in nomenclature. From August 2020, what was previously known as the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man has been officially renamed the “National Joint Registry” a change that will lead editors and authors alike to breath a collective sigh of relief over word counts, particularly in titles and abstracts.

Non-arthroplasty

August 2020 saw the publication of the first article arising from the UK Non-Arthroplasty Hip Registry (NAHR) which looked at periacetabular osteotomy (PAO) for developmental dysplasia of the hip and femoroacetabular impingement (FAI).¹ In this study, published in JBJS Am, the authors identified 630 PAOs performed between January 2012 and February 2019 and then reported EQ-5D and iHOT-12 scores pre-operatively and at six months, 12 months and two years post-operatively. This retrospective observational study included all patients undergoing a single stage PAO within the period specified, if performed for DDH or FAI secondary to acetabular retroversion and with a Tonnis grade of 0 or 1. Eleven surgeons contributed data to the analyses with three surgeons contributing

90% of all cases. Overall, 87.5% of patients were available for follow-up at six months with 74.3% available at 12 months and 55.4% at two years with a slightly higher proportion of patients in the FAI group being available at longer follow-up points. The minimum important difference in iHOT-12 score was set at ≥ 9 points and this improvement was achieved in both DDH and FAI groups by 77.9% and 76.9% of patients not lost to follow up after six months. These results led the authors to conclude that PAO is an effective surgical treatment for patients with symptomatic DDH of FAI due to acetabular retroversion. The loss to follow-up and limited number of surgeons contributing to this study are clear weaknesses, however it does represent the early years of data collection and we expect that as the database matures, more surgeons will contribute making future findings more generalisable. As lessons are learnt regarding data collection the loss to follow up with hopefully reduce. The authors commendably performed sensitivity analyses to investigate whether those patients lost to follow up were more likely to have been unhappy, but it is still possible that patients with poor outcomes withdrew for that reason. This study is limited by the same weaknesses of all registry analysis in that it is not possible to draw causal inference but only suggest association between exposure and outcome. In addition, it is not clear what proportion of contributing surgeon's cases were entered into the register, so may be subject to selection bias. In our opinion, the conclusions seem valid in that most patients that were selected for surgery, entered onto the register and not lost to follow up appeared to show improvements in EQ-5D and iHOT-12 above the minimally important clinical difference. We also feel that this is an important article for those surgeons interested in non-arthroplasty hip surgery and is a success of the registry and those that have worked hard to set it up.

Hip

One of the most important articles to be released in recent months is the protocol for a randomised controlled trial nested within the Dutch Arthroplasty Registry.² In this study the authors aim to investigate the effectiveness of dual mobility cups compared with uni-polar cups for preventing dislocation after primary hip arthroplasty in elderly patients. The population for this study will be

patients over 70 years of age undergoing total hip replacement (THR) using the posterior approach and a cup size that allows a 32 or 36mm femoral head. The study uses dislocation by three months, one year and two years as its primary outcome with PROs evaluated at the same time points. The exclusion criteria do cause some concern given patients with “epilepsy, spasticity, dementia, mental retardation, or alcoholism” to be excluded, a cohort generally considered by many to be at high risk of dislocation and therefore a population where dual-mobility cups are often considered. It may also be relevant that the power calculation for this study was based on articles that included these “high risk” patients and therefore may be at risk of a smaller effect size than previously reported and as such be underpowered. The limitation on femoral head size also limits how many patients can be recruited; having reviewed the Dutch registry report we estimate that 10-15% of patients would not be eligible based on head size alone, which may cause issues with recruitment and generalisability. The nested design of this study means that long after the two year follow-up period ends the cohort can be monitored for the outcomes of revision and mortality, a concept that increases the efficiency of the study and allows for long term reporting without the need to maintain contact with patients individually. Putting the above concerns aside, this is an impressive and important study and one which we eagerly await the results of.

In August 2020, Blom et al. published their analysis of over 700,000 elective THRs in the NJR in which they sought to compare different approaches to the hip.³ The population was patients undergoing primary THR with osteoarthritis (OA) as an indication and the comparator or reference group was those THRs where a conventional posterior approach was used. The outcomes of interest were revision, short term mortality and PROMS including EQ-5D and Oxford Hip Score. In models adjusted for age, sex, additional indications (as well as OA), ASA, fixation, year of primary and head size the authors observed an association between the use of a conventional lateral, minimally invasive lateral, minimally invasive anterior and trans-trochanteric approaches and increased hazard of revision. When BMI was also added in as a co-variate the association only remained for the conventional lateral approach. There were no clinically relevant differences in PROMs between the different approaches, but the conventional lateral approach was associated with a higher risk of 90-

day mortality (HR 1.15 95% CI 1.01, 1.3). This study, the largest of its type looking at approaches in THR supports the continued use of the conventional posterior approach and suggests that large, well designed studies will be needed to assess any potential benefit from either minimally invasive posterior or conventional anterior approach.

Knee

January 2020 saw the publication of a comparison of conventional polyethylene and highly cross-linked polyethylene (HXLPE) in primary total knee replacement (TKR) in the JBJS by Partridge et al.⁴ The authors analysed data recorded in the NJR of 550,658 TKRs implanted between 2003 and 2014 to principally compare rates of aseptic revision. The analyses focus on a within brand comparison of three commonly used TKR prostheses (Nexgen, PFC Sigma and Triathlon) to account for the fact that implant brands may demonstrate differing survival results. In the comparison of TKRs with conventional polyethylene and those using HXLPE there was no observed difference in the overall hazard of revision for any of the three chosen TKR prostheses. The authors note that the use of (the more expensive) HXLPE is increasing in the NJR and conclude that this study suggests there is no survival benefit in using HXLPE up to 12 years. Sub-group analyses of patients under 60 years of age and those with a BMI >35kg/m² who had a Triathlon TKR did suggest some overall survival benefit in the use of HXLPE which leads the authors to conclude that further work is needed to assess the potential benefit of using HXLPE in these cohorts. The study is prone to selection bias, given that patients were selected for the implant rather than randomised and as the study is observational, we can only discuss the association of polyethylene type and survival and not draw conclusions that any difference in survival is caused by the type of polyethylene used. Most importantly however, given the high survival expected of TKRs in the long-term, greater follow-up may be required to demonstrate any difference between the groups analysed in this study.

In an interesting study published in Acta Orthopaedica, El-Galaly et al. analysed the Danish Knee Arthroplasty Registry to investigate the survival of TKR following either High Tibial Osteotomy

(HTO) or medial unicompartmental knee replacement (UKR).⁵ The authors included 978 TKR following UKR and 1,155 following HTO and used revision for any cause as their outcome. Analyses adjusted using a propensity score matching technique, showed a 2.7 times increased hazard of revision of TKRs for any cause following UKR compared to HTO (HR 2.7 95% CI 2.4, 3.1). Given the relatively low numbers included in this study, it is prone to residual confounding and there may also be some issues with completeness of reporting of which TKRs had previously had a HTO as these data were not available within the registry unlike the UKR group. Whilst interesting, the premise of this study is to aid decision making for patients who are eligible for both UKR and HTO. This may be a somewhat limited group, but this study does provide useful information to both patients and surgeons. The authors conclude that UKR “should be considered a definitive treatment in line with TKA rather than a temporary treatment to postpone TKA”, a sentiment that we agree with.

Shoulder

August saw the publication of our own meta-analysis written in collaboration between the Universities of Exeter Oxford and Bristol and published in The Lancet Rheumatology. In this study we reviewed the survival of shoulder replacements past 10 years in both case-series and registries.⁶ The pooled ten year survival of both total anatomic shoulder replacement and hemi-arthroplasty was over 90% when data were extracted from case-series. Only one registry (the Australian Orthopaedic Association National Joint Replacement Register (AONJRR)) contributed data and when weighted by construct, the pooled 10 year survival of anatomic total shoulder replacement was 92.0% (95% CI 91.0, 93.0) and 85.5% (95% CI 83.3, 87.7) for humeral hemi-arthroplasty. Reverse total shoulder replacement was stratified by indication, with those performed for osteoarthritis demonstrating a 94.4% (95% CI 93.4, 95.7) 10-year survival and those performed for rotator cuff arthropathy 93.6% (95% CI 91.1, 95.8)). These results are reassuring for patients and surgeons alike, however they need to be interpreted with caution as the fact a joint replacement has not been revised does not necessarily mean it is a success if there is not a viable revision option. The study did however go on to review the Patient Reported Outcomes (PROs) reported in case-series and showed a substantial and sustained

improvement from baseline scores at 10 years. One of the key findings of this study, however, was the paucity of long-term survival results reporting results stratified by construct and published in registries. Reporting by construct is key given the fact different implant designs can be expected to demonstrate different survival results when used in combination, in a similar way to what has been previously observed in hip and knee replacement.^{7,8} In view of this we encourage registries to report survival by construct. The reporting of PROs was also limited in registries. Only the New Zealand registry reported PROs by construct, but with no baseline scores to compare to, interpretation of this data is challenging. The reporting of PROs by registries, particularly for shoulder replacement, is important and we hope will become more commonplace in the future.

Conclusion

2020 continued to be an interesting year for registry research with articles published in a variety of general interest journals as well as traditional orthopaedic ones. We eagerly await more research from the impressive Non-Arthroplasty Hip Registry as well as other registries such as the Bone and Joint Infection Registry as their data mature.

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